



Government of the District of Columbia
Department of Health



State Health Planning and
Development Agency

May 31, 2013

Richard O. Davis, Ph.D.
President
Sibley Memorial Hospital
5255 Loughboro Road, N.W.
Washington, D.C. 20016-2695



**Re: Establishment of Proton Therapy Services - Certificate of Need Registration
No. 12-3-10**

Dear Dr. Davis:

The D.C. State Health Planning and Development Agency (SHPDA) has partially approved your application for a Certificate of Need (CON) as referenced above. A statement of findings and the Certificate of Need are enclosed.

Please note that any person may request reconsideration of the review decision within 30 days of this decision. The SHPDA may grant a reconsideration request upon demonstration of "good cause", as defined in D.C. Official Code § 44-412 (b) and Certificate of Need Regulations, 22 DCMR Section 4312.

Thank you very much for your cooperation during the review period. If you have questions concerning this matter, please do not hesitate to contact me.

Sincerely,

Amha W. Selassie
Director

AS:dlm

Enclosures

cc: Sharon Lewis
Linda Elam



**Government of the District of Columbia
Department of Health**



**State Health Planning and
Development Agency**

**DISTRICT OF COLUMBIA
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
Notice of Official Action
Certificate of Need
Number 12-3-10**

Sibley Memorial Hospital is hereby awarded this Certificate of Need in conformance with the District of Columbia Certificate of Need statute, D.C. Official Code § 44-401 et. seq. for the establishment of proton therapy services with two treatment rooms. The request to provide proton services to pediatric patients, however, is denied.

This issuance is based on all specifications contained in the Certificate of Need application and related documents in the record. Deviations from the specifications are allowable pursuant to the statute. The capital expenditure associated with this project is \$129,900,000. The State Health Planning and Development Agency herewith makes all findings applicable to this issuance as required by the statute.

The certificate of need is issued contingent on the following conditions:

- Given the incidence and prevalence of cancer in the District of Columbia and given the health disparities in the District, the Applicant must, in consultation with the Department of Health, establish, operate and maintain a new full time cancer screening and treatment clinic in one of the underserved areas of the District in Ward 5 or 8, particularly to prevent and treat the most common cancers – breast, lung, prostate and colorectal - and provide a clear plan of implementation with its second quarterly progress report;
- In order to ensure that underserved, uninsured, under insured, and minority patients have access to proton therapy treatment, the Applicant must enter into clear arrangements with the D.C. Primary Care Association, clinics, hospitals, and other entities that serve these patients and establish mechanisms to facilitate access to the proton therapy services and report to the SHPDA with its first year progress report ; and

- Provide to SHPDA annually information on the proton therapy utilization and on the operations of the cancer screening and treatment clinic, including the number of patients served, the diagnosis, source of payment, source of referral, as well as the race, age, sex, ward, and zip code of the patients.

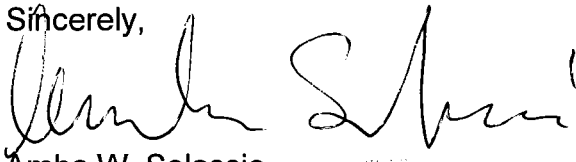
This Certificate of Need is valid until May 31, 2016 unless: (1) its issuance is revoked following a public hearing held for reconsideration of this issuance in accordance with DC Official Code § 44-412, or further proceedings in accordance with DC Official Code § 44-403 or 44-414; (2) it is withdrawn in accordance with DC Official Code § 44-411; or (3) it is terminated because the State Health Planning and Development Agency has certified that operations may begin, in accordance with DC Official Code § 44-409.

Unless this Certificate of Need has been revoked, withdrawn, or terminated, quarterly progress reports must be submitted to the State Health Planning and Development Agency on August 31, 2013, November 30, 2013, February 28, 2014, and May 31, 2014. The reports should also be submitted quarterly every year until the project is completed.

Notification of the proposed date for the initiation of operation of the facility or service approved here in should be provided to the State Health Planning and Development Agency no later than thirty days prior to the proposed date for the initiation of operation so that the review required by DC Official Code § 44-409 may be conducted.

Signed this 31st day of May, 2013.

Sincerely,

A handwritten signature in black ink, appearing to read 'Amha W. Selassie', written over a horizontal line.

Amha W. Selassie
Director

AS:dlm



Government of the District of Columbia
Department of Health



State Health Planning and
Development Agency

DISTRICT OF COLUMBIA
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY
CERTIFICATE OF NEED REVIEW
FINDINGS IN THE MATTER OF:
SIBLEY MEMORIAL HOSPITAL
CERTIFICATE OF NEED REGISTRATION NO. 12-3-10

The findings contained in this document were developed in conformance with Certificate of Need (CON) review criteria required by D.C. Official Code § 44-409, and contained in regulations, 22 DCMR B4050 et. seq. These findings reflect my assessment of the information in the project record, and its consistency with the applicable considerations, standards, and criteria for CON review. These findings are based on all specifications contained in the CON application and all related documents and testimony submitted to the record.

The findings take into account the recommendations of both the Project Review Committee (PRC) and the Statewide Health Coordinating Council (SHCC) in their respective deliberations on March 21, 2013, April 18, 2013, and May 16, 2013.

A. Overview of the Applicant and the Proposed Project:

Sibley Memorial Hospital is a non-profit community hospital located in upper Northwest Washington D.C. Sibley traces its history to 1890 when the Lucy Webb Hayes National Training School for Deaconesses and Missionaries was founded by the Woman's Home Missionary Society of the Methodist Episcopal Church in Washington, D.C. The current Hospital site on Loughboro Road, N.W. was acquired through Congressional legislation in the 1950s, and a hospital was built and opened to serve patients in 1961. In 2010, Sibley was affiliated with the Johns Hopkins Health System Corporation (JHHS) and

became a member of Johns Hopkins Medicine (JHM). The Hospital's mission is "to provide quality health services and facilities for the community, to promote wellness, relieve suffering, and restore health as swiftly, safely, and as humanely as it can be done consistent with the best service we can give at the highest value for all concerned". The Hospital is currently building a new bed tower and emergency room, and has constructed a new cancer center.

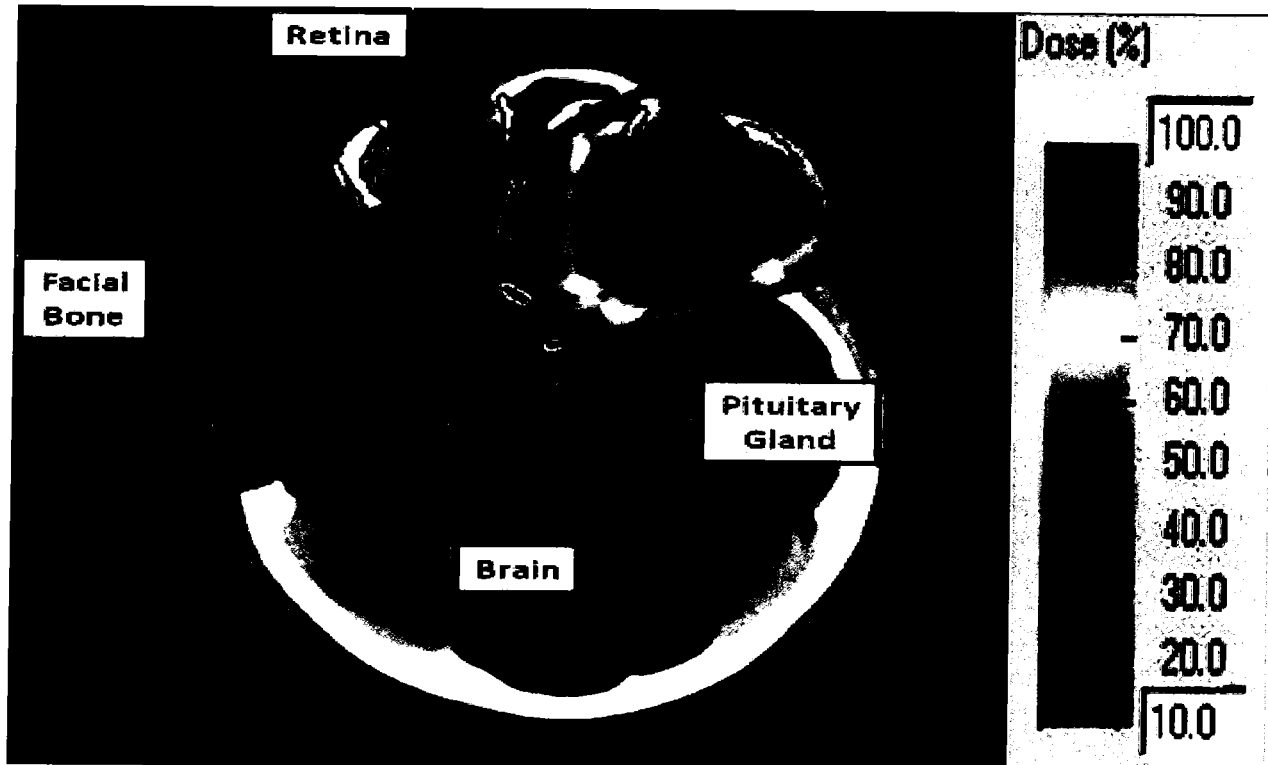
The Applicant states that, when Sibley became affiliated with JHM, the parties agreed to prioritize the growth and enhancement of several clinical services and programs. The expansion of oncology services was specifically identified as a high priority. The Applicant maintains that after the partnership was finalized in 2010, collaborative strategic planning focused on growth in new oncology services at Sibley and the integration of the existing oncology programs at the Hospital with programs at JHHS. The Applicant states that clinical oncology is being improved through collaborative partnerships and programming in radiation oncology and medical oncology, providing the Sibley community with access to an expanded infusion center, the latest radiation oncology technologies and services, and to new clinical trials. According to the Applicant, research through clinical trials across all clinical services is now standardized between Sibley and JHM, making the infrastructure, expertise, and experience of JHM available at Sibley to improve clinical trial access and quality.

The Applicant is now proposing the establishment of a proton therapy center on the Sibley Hospital campus. Proton therapy is a type of particle therapy which uses a beam of protons to irradiate diseased tissue, most often in the treatment of cancer. The Applicant maintains that proton therapy starts with the injection of hydrogen atoms into an accelerator. Using magnetic fields, the atoms are accelerated in a circular motion. During this time, the hydrogen atoms shed their electrons, leaving behind only positively charged protons. Billions of protons are accelerated to nearly the speed of light, which generates the proton beam. The proton beam is then controlled to treat the patient. In contrast, the Applicant states that photon radiation is generated by the interaction of accelerated electrons and a heavy metal. The linear accelerator speeds up the

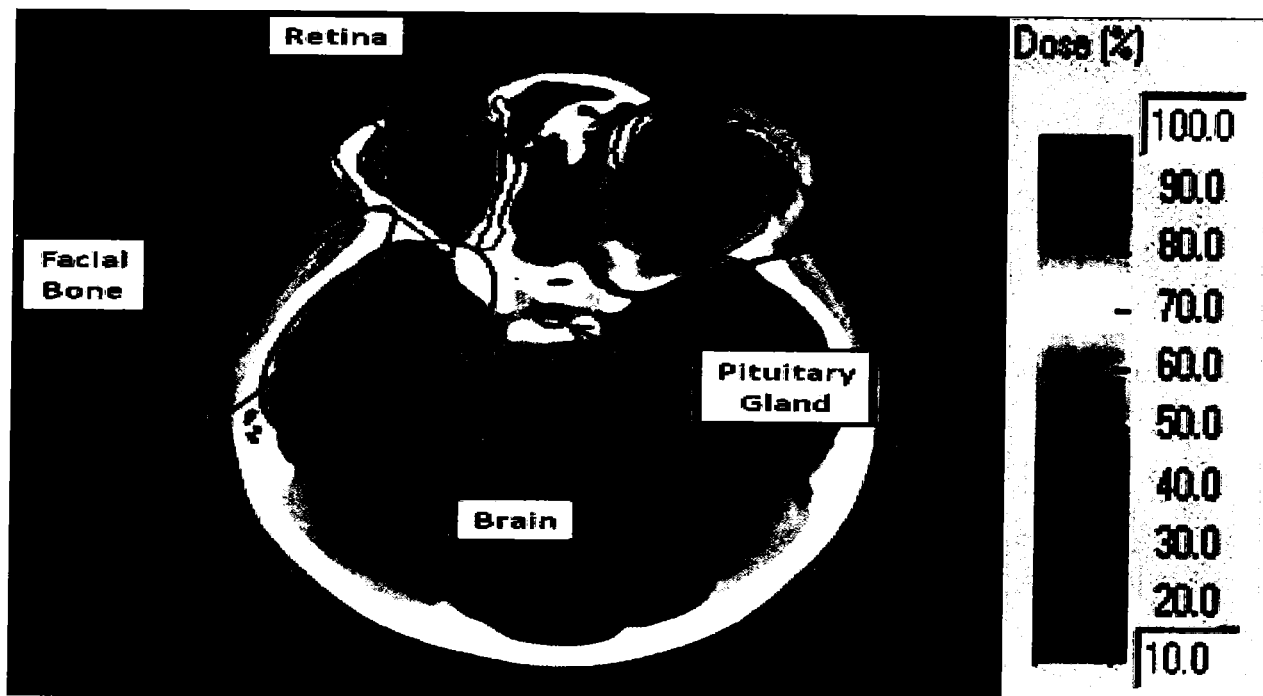
electrons, and these electrons are directed to strike and interact with a heavy metal target, often tungsten. The result of the interaction is the generation of photon radiation, also called x-ray radiation. X-rays are photons like light and have no mass. However, photon radiation used to treat cancer has energies that are several million times higher than light. Along the way, the photon radiation deposits small amounts of energy or radiation dose that ionizes human tissue in its path. As a result, photon radiation therapy is indiscriminating in causing damage to healthy tissue upstream of the tumor, the tumor, and healthy tissue downstream of the tumor. Unlike a photon beam, the proton beam has mass, and therefore has a finite range of penetration into a human body depending on its energy. In addition, nearly all of the ionizing radiation is delivered at the end of its path. When comparing the proton beam path to that of the photon beam, the proton beam deposits less dose at the point of entry into the body and upstream of the tumor. Maximum dose is delivered to the tumor where the proton beam stops, and, finally, because the beam stops at the tumor, there is no dose downstream of the tumor.

According to the Applicant, proton therapy is a complimentary modality of Radiation Oncology that can be used for the treatment of tumors in adults and pediatrics. Proton Therapy has a significant advantage over photon therapy in that the radiation dose of the proton beam can be controlled with extreme precision, targeting nearly all the radiation to the cancer cells and only minimally exposing healthy tissue. The increased dose control improves targeting of tumors, ability to spare healthy tissues, reduce toxicities and related side effects. The Applicant states that the advantages of proton physics over conventional radiation physics are ideal for pediatric cancer populations, because children have a potentially long life expectancy. Pediatric patients may be more susceptible to secondary malignancies from conventional radiation. Proton therapy offers an alternative especially where sparing surrounding healthy tissue is critical, such as intracranial, spine, neck, abdominal, and lung tumors. The Applicant has provided an example of photon and proton therapy to demonstrate the differences in dose distributions of a pediatric patient:

Conventional Radiation



Proton Therapy



The above pictures show that:

- Nearly the entire proton radiation dose is deposited at the site of the tumor, which results in a higher dose of radiation to the tumor, and a dose that conforms to the shape of the tumor.
- There is no exit dose. Unlike the conventional radiation path shown above, the proton therapy beam is stopped at the site of the tumor. In the proton therapy case there is no exposure to the pituitary gland, the healthy eye, or to the healthy facial bone. Also, the majority of the healthy brain tissue avoided any radiation dose, which also means no exposure to the vasculature in the brain.
- The risks of long term effects of radiation treatment to the pediatric patient in this example are minimized if not completely eliminated. The patient has a significantly greater likelihood of leading a long, high quality life, free of radiation toxicity side effects.

The Applicant states that proton therapy is primarily used for diagnosed tumors of the central nervous system, eye, pituitary, base of the skull or axial skeleton, head and neck, lung for sarcomas, and for pediatric solid tumors. Prostate cancer is treated on a case by case basis. The Applicant projects that through clinical trials, and studies of proton therapy treatment, protocols for other types of cancer such as pancreatic cancer, liver cancer, and breast cancer will be developed.

According to the Applicant, Sibley will partner with the Sidney Kimmel Comprehensive Cancer Center (SKCCC), the center for cancer research at JHHS which is a National Cancer Institute (NCI) designated comprehensive cancer center. The SKCCC manages \$197 million in cancer research funding, of which \$84 million is grant funding from NCI. The funding supports cancer biology and cancer care research programs that are focused on new discoveries in cancer screening, cancer prevention, and cancer care. The SKCCC is currently managing 267 clinical trial studies, and enrolled 1,657 patients

to clinical trials in 2011. As a result, 27% of the new cancer cases seen by the SKCCC were provided unique care protocols offered through clinical trial research studies. The Applicant emphasizes that clinical cancer research is integral to the contemporary care that will be provided and that Sibley is committed to the discovery of new treatments that will increase the effectiveness and quality of care for patients with cancer.

The Applicant asserts that Sibley in conjunction with JHHS is committed to developing and maintaining innovative research and Proton Therapy-based programmatic education and training of clinical oncology providers. The Applicant states that Sibley is in the process of implementing a strategy to deliver these commitments by formalizing strategic, mission-based partnerships in proton therapy with the following facilities:

Children's National Medical Center (CNMC) - Sibley and Johns Hopkins will partner with CNMC to develop a comprehensive pediatric radiation oncology program at Sibley. Sibley, CNMC, and Johns Hopkins will develop a multi-disciplinary pediatric oncology program that will provide the District of Columbia's pediatric oncology patients with access to world class oncology providers, to coordinate pediatric oncology programming under the leadership of specialty trained pediatric oncologists, and to collaborative clinical trials. CNMC will partner with Sibley to bring proton therapy to the pediatric cancer community in Washington, D.C. so that patients and their families will have local access to proton therapy and not have to be displaced from home for weeks at a time while seeking proton therapy care outside of the region.

Howard University Hospital (HUH) - Sibley, Johns Hopkins and HUH will work to develop collaborative programming that provides proton therapy access to HUH cancer patients, that grows current collaborative research to include proton therapy, and that develops training opportunities for oncologists, medical physicists, other clinical professional, and undergraduate and graduate students.

All Children's Hospital - All Children's Hospital is a John Hopkins pediatric hospital located in Tampa, Florida. All Children's Hospital does not have access to proton

therapy in Tampa, and patients must be referred to out-of-area proton therapy centers such as Massachusetts General Hospital, MD Anderson, and University of Florida. All Children's, Sibley, and the Johns Hopkins University School of Medicine have executed a memorandum of understanding to develop a collaborative program which will provide access to Johns Hopkins proton therapy and tertiary radiation therapy at Sibley through the collaborative multidisciplinary management of cancer patients, and which will establish collaborative research and training programs in pediatric oncology.

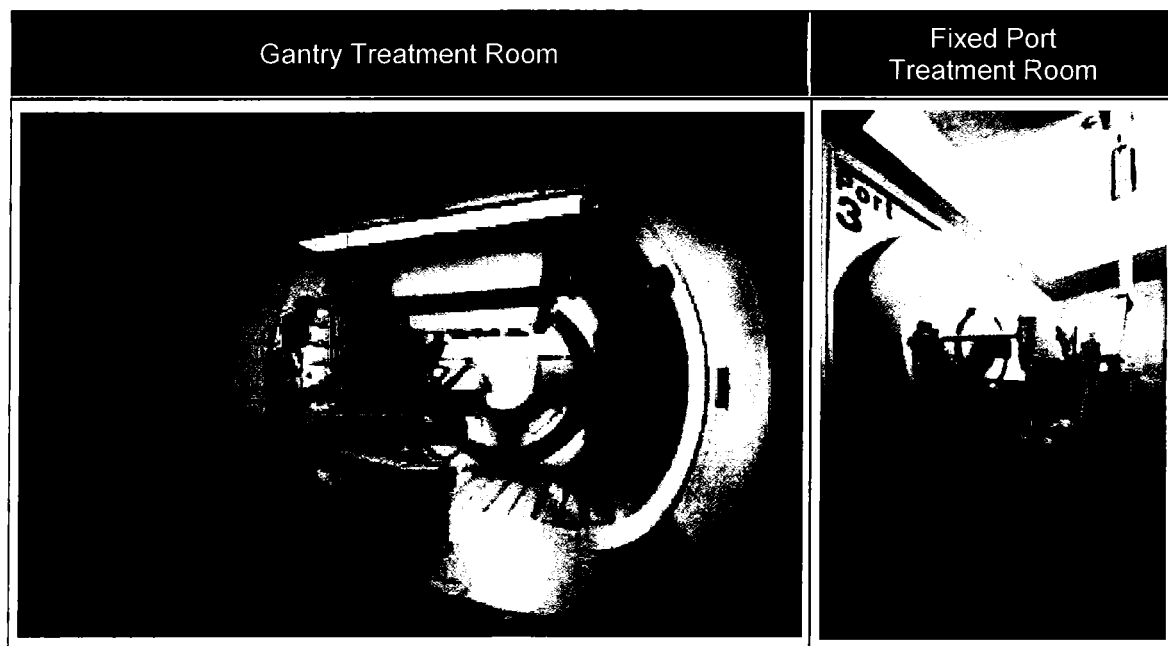
American University (AU) - AU, Sibley and Johns Hopkins are exploring a partnership that would provide opportunities in medical physics research and training for AU undergraduate and graduate physics students at Sibley.

Walter Reed National Military Medical Center (WRNMMC) and the National Cancer Institute (NCI) - WRNMMC, NCI, Sibley and Johns Hopkins have initiated discussions to explore opportunities to develop clinical trial research and laboratory research collaborations in the study of proton therapy at Sibley and carbon therapy at the proposed Carbon Therapy Center at WRNMMC. WRNMMC, NCI, Sibley and Johns Hopkins have initiated discussions to explore opportunities to develop a collaborative medical physics clinical and research program in proton therapy at Sibley, and carbon therapy at WRNMMC.

WellSpan Health - WellSpan Health is an integrated health system that includes cancer programming at WellSpan York Hospital and WellSpan Gettysburg Hospital. The WellSpan cancer program provides clinical services to 2,400 new cancer patients annually. WellSpan and Johns Hopkins have had a long-term partnership that includes The Johns Hopkins Hospital as the primary tertiary referral site for WellSpan's cancer patients. Sibley, Johns Hopkins, and WellSpan are formalizing partnership planning that will expand the current relationship to include the Sibley proton therapy center as a referral site for WellSpan's proton therapy patients.

The proposed capital expenditure is \$129,900,000, and the project is scheduled to be completed in 2017. The proposed proton therapy center will be located in the northwest corner of Sibley's campus, bounded by Little Falls Road to the north, the existing service drive to the south, the new service drive and ambulance entrance to the east, and the parking garage to the west. The proposed footprint of the center will include approximately 22,000 square feet of new construction. The building will be a reinforced, poured in place concrete superstructure, walls, roof, floor slabs, footings, and foundations. Due to the shielding thicknesses for the vaults, proton generator, beam path, and access corridors, the concrete shielding will be up to 14 feet thick. The building footings will be engineered to withstand weights of approximately 200 tons. The Applicant maintains that the building facade will be designed to fit within the current architectural design of the campus.

Sibley proposes to purchase a cyclotron-based proton therapy system that supports four treatment rooms from Sumitomo Heavy Industries. Three of the treatment rooms will be equipped with 360 degree rotational gantries and will be utilized 100% for clinical care. The fourth treatment room will be a fixed beam treatment room, which means that there is a treatment port that is not supported by a gantry, and thus cannot rotate around the patient. The Applicant states that Sumitomo, like most proton therapy vendors, produces and sells custom proton therapy systems that are built to fit the specifications of its customer. Though the individual components of the proton therapy system are standardized, these components can be combined and assembled in a variety of products that meet the specific needs of the customer. Sumitomo manufactures and assembles all major components of their proton therapy system. The Sumitomo proton therapy system at the National Cancer Center Hospital in Japan was the first clinically operating proton therapy system in Japan and the second hospital based operating system in the world. Below are pictures that show what the different rooms would look like.



B. Review Findings and Conclusion

1. Need for the Proposed Project:

The Applicant states that the development of the Sibley Proton Therapy Center is an exciting next step in the collaborative expansion of oncology services at Sibley. The project will create opportunities for researchers to conduct cutting-edge research, and shape future advancements in oncology care. The project will create training opportunities for JHM trainees and students, fellows, or medical personnel at several other institutions across the Washington, D.C. area. The Applicant maintains that, primarily, this project will bring a life-saving therapy to the Washington DC area for all patients. According to the Applicant, Sibley and JHHS are committed to the development of the Sibley Proton Therapy Center, which will require significant investments in multi-disciplinary clinical expertise, capital equipment, infrastructure, and research capabilities.

The Applicant states that over the past forty years, more than 50,000 patients globally have been treated with an alternative to conventional radiation therapy - proton therapy.

Although proton therapy has been used for clinical treatment for over 40 years, the Applicant reports that clinical trial research has been limited to few peer reviewed studies with small numbers of patients. Most of the publications are based on single institution studies, and many are not randomized controlled trials. The Applicant states it reviewed scientific evidence for the use of proton beam therapy to treat central nervous system malignancies, lung cancer, gastrointestinal cancer, ocular melanoma, prostate cancer, head and neck cancer, and pediatric malignancies. The general theme of the disease site specific review is a lack of clinical data and studies, and that more robust clinical trials are needed to determine the appropriate clinical setting for proton therapy.

The articles reviewed by the Applicant discuss proton therapy efficacy for certain tumors as follows:

An article by Christine E. Hill-Kayser, Stefan Both and Zelig Tochner titled “Proton therapy: ever shifting sand and the opportunities and obligations within” indicates the following:

Central Nervous System

- 2004 St. Clair and colleagues study indicated reduced dose to the cochlea and heart for medulloblastoma patients;
- 2008 Merchant and colleagues study indicated a reduction in IQ deficit for childhood brain tumors; and
- Massachusetts General Hospital (MGH) studies for ependymoma and CNS germ cell tumors showed strong overall survival accompanied by substantial normal tissue sparing as compared to IMRT.

Skull Based and Head and Neck

- Strong data particularly from the Paul Scherrer Institute for treating skull based chordomas and chondrocarcomas;

- Several studies have indicated better normal tissue sparing for paranasal sinuses, nasopharynx, and oropharynx/hypopharynx/larynx; and
- MGH has several studies showing evidence of normal tissue sparing for pediatric cancers of the head and neck.

Abdomen and pelvis

- A study by Zietman et. al, 2005 indicated that proton therapy was able to reduce side effects using dose escalation with proton therapy.

Chest/Lung

- Dose escalation with proton therapy showed excellent results for early stage lung cancer;
- Dosimetric comparisons with photon based Stereotactic Body Radiation Therapy (SBRT) indicated better protection of organs at risk, including uninvolved lung;
- Data from MD Anderson is indicating reduced dose to lung, esophagus, heart, and coronary arteries for the treatment of mediastinal lymphoma; and
- Pediatric Note – The author states that for pediatric specific tumors, “It is in the opinion of these authors that proton therapy should be considered and utilized for all pediatric patients needing curative irradiation”.

The report of American Society for Radiation Oncology’s (ASTRO) emerging technology committee titled “An evidence based review of proton beam therapy” reviewed the data for proton efficacy of certain tumor sites:

Central Nervous System

- Planning studies indicate similar or better Planning Target Volume (PTV) coverage with proton therapy with substantially improved critical structure avoidance and total integral dose;
- Local control of chordomas is approaching 80%, which is better than conventional photon therapy; and
- New clinical data indicating proton therapy or mixed photon/proton therapy appear superior for base of skull tumors as compared to photon therapy.

Lung

- Data suggests local control rates of 80-90% with proton therapy, which is similar to photon based SBRT; and
- Data is limited and insufficient.

Gastrointestinal

- Strong data out of Japan for HCC (hepatocellular carcinoma) with local control rates between 70% and 85%; and
- Proton therapy for GI malignancies is mostly untested.

Ocular Melanoma

- Thousands of cases in the literature for the treatment of ocular melanoma with proton therapy;
- 95% local control rate and 90% eye retention rate; and
- Proton therapy has been shown effective.

Prostate Cancer

- Approximately 2,000 proton therapy cases reported in the literature;
- Dosimetric studies indicate superior normal tissue sparing using low to moderate dose ranges; and
- Data does not show a clear advantage between proton therapy and IMRT in disease control or prevention of late toxicity.

Head and Neck Cancer

- Proton therapy well suited to treat targets near critical structures, especially for base of skull tumors; and
- Further clinical data from prospective clinical trials are needed.

Pediatric Cancers

- Dosimetric studies clearly demonstrate superior normal tissues sparing and decreased integral dose;
- McDonald et al. – excellent outcome in ependymomas with proton therapy while sparing cochlea, hypothalamus, and temporal lobes;
- MGH study comparing the rate of secondary malignancy for 1450 adult patients treated with proton therapy and a matched cohort from the Surveillance Epidemiology and End Results (SEER) database; and
 - 6.4% rate of secondary malignancy for the MGH proton therapy patients as compared to 12% for the matched SEER database cohort; and
 - Of the 15 pediatric patients, none developed secondary malignancy.
- Data is insufficient to determine superiority for non-central nervous system pediatric malignancies.

The proposed Sibley proton therapy center will have three rooms dedicated to clinical treatment, one for pediatric cancer patients and two for adult cancer patients. The fourth room will be used primarily for innovative treatments on protocol, research, discovery, and development. The Applicant maintains that it will serve three distinct markets: Regional Service Area (RSA), Other Domestic Service Area (ODSA), and International Service Area (ISA). According to the Applicant, the definition of the RSA for the proposed project was determined by the study of the service areas covered by some existing and under development proton therapy centers.

1. Provision Center for Proton Therapy, Knoxville, TN - The Knoxville facility projected its primary service area to be a 150 mile radius from Knoxville, which includes a population of 4 million and is expected to generate 55% of patient volume for their three treatment room facility.
2. MGH Burr Proton Center- 2009 data provided by Massachusetts General Hospital (MGH) indicates that 77% of their patient volume is generated from the New England market. The 2010 U.S. Census Bureau Data shows that the population of New England is 14 million people.
3. University of Florida - Data presented in a 2007 bond application showed that 32% of the University of Florida's three treatment room Proton Therapy Center's patient population was from within a 60 mile radius of the proton center, and 73% of the proton center's patient population was from within a 300 miles radius.

According to the Applicant, using the experience of the established and successful MGH and Florida Proton Centers as a guide, Sibley has defined the RSA for the Sibley Proton Therapy Center to include counties within a 100 mile radius of Sibley Memorial Hospital, which includes a population of 14.3 million people. The RSA includes Washington, D.C., Northern Virginia, Central Maryland, Southern Pennsylvania, Delaware, and small portions of West Virginia and New Jersey. The Applicant estimates

that approximately 70% of the Sibley Proton Therapy patients will be generated from this RSA.

The Applicant maintains that the ODSA is defined as all other market areas in the United States that are not included in the RSA. About 20% of the proton therapy patients are expected to come from the ODSA. The Applicant states that this projection is consistent with the actual experience of MGH Burr Proton Center, which shows that 16% of their patient population is from other U.S. markets outside of New England. It is also consistent with the markets served by The Johns Hopkins Hospital, where across all clinical programs 19% of inpatients seeking the expertise of Johns Hopkins University sub-specialized physician faculty originate outside of the State of Maryland.

The Applicant states that the ISA is defined as all markets outside of the United States which is projected to comprise 10% of the Sibley proton therapy patients. This projection, the Applicant maintains, is consistent with the experience of MGH Burr Proton Center, and is reasonable given Sibley's location in Washington, D.C., and also given the relationships JHM has established to serve international patients.

The Applicant states that the Health Care Advisory Board, a global research, technology and consulting firm, has published a report entitled "Proton Beam Therapy - Energizing Technologies and Market Opportunities". This report presents a model for projecting need for Proton Beam Therapy by using the cancer incidence rate to determine the projected number of proton treatment rooms needed for a defined population. The Applicant maintains that Sibley applied the Advisory Board Report model to the RSA which includes the 100 mile radius surrounding Sibley and concluded that there was a need for 16.4 treatment rooms. In the Advisory Board Report model, the projected number of new cancer patients is calculated using data from the NCI SEER Cancer incidence rate based on 100,000 population. This is followed by a calculation of the number of patients that are expected to receive radiation treatment (50%) and then further divided by the percentage of patients thought to be eligible for proton therapy (15%). The following chart shows the calculation for Sibley's RSA:

State	2010 Population	Total Cancer Incidence Rate	Projected New Cancer Patients	Projected Radiation Patients	Projected Proton Eligible Patients	Number of Treatment Rooms Needed
Washington DC	601,723	459.2	2,763	1,382	207	0.8
Delaware	897,934	516.3	4,636	2,319	348	1.2
Maryland	5,692,001	453.0	25,784	12,895	1,934	6.4
New Jersey	222,981	501.4	1,118	599	84	0.4
Pennsylvania	2,497,891	480.2	11,994	6,000	899	2.8
Virginia	4,177,429	437.4	18,272	9,149	1,375	4.4
West Virginia	241,409	461.0	1,113	558	84	0.4
Total RSA	14,331,368	458.3	65,680	32,862	4,931	16.1

The Applicant adds that the Advisory Board assumption for the radiation rate of 50% is conservative because the American Society for Radiation Oncology (ASTRO) projects it closer to 66% and the projection by the NCI is about 60%. Using the NCI data, the Applicant states that 19.7 treatment rooms would be needed, and 21.7 treatment rooms will be needed if one uses ASTRO's projections. Additionally, the Applicant maintains that the above projections are calculated assuming static demand for proton therapy services and do not account for growth in demand over the next 10 years. The Applicant notes that Sg2 Health Care Intelligence, a firm that provides advanced analytics, business intelligence, and education, projects that radiation therapy services are expected to grow by 22% in the next ten years based solely on population growth.

Need Model	2010 Projected Eligible Proton Therapy Patients	Sg2 Projected 10 year Growth Rate	2020 Projected Eligible Proton Therapy Patients	2020 Projected Treatment Rooms Needed
Advisory Board Model	4,931	22%	6,016	20.8
ASTRO Projection	6,500	22%	7,930	26.4
NCI Projection	5,900	22%	7,198	24.0

The Applicant also states that Sibley conducted an analysis of established proton therapy centers to determine the need for proton services. Sibley used the Metropolitan Statistical Area (MSA) defined by the US Office of Management and Budget and population data to determine the total population per proton treatment room. The following chart shows Sibley's findings:

Proton Therapy Center	Year of Operation	Treatment Rooms	MSA	MSA 2010 Population	Population per Treatment Room
Loma Linda University	1990	4	Riverside-San Bernardino-Ontario	4,224,851	1,056,213
Massachusetts General Hospital	2001	4	Boston-Cambridge-Quincy	4,552,402	1,138,101
Midwest Proton Radiotherapy Institute	2004	3	Bloomington-Indianapolis-Carmel	1,948,955	649,652
M.D. Anderson	2006	4	Houston-Sugar Land-Baytown	5,946,800	1,486,700
University of Florida	2006	3	Jacksonville	1,345,596	448,532
Average		3.6		3,603,721	955,840

Washington DC MSA – (DC, MD, VA, WV) 2010 Population	5,582,170
Population per Treatment Room	955,840
Treatment Room Capacity for the DC MSA	5.8

The Applicant further notes that there are multiple proton therapy centers in close proximity to each other and in the same MSA throughout the United States.

City	Proton Therapy Center 1	Proton Therapy Center 2	Distance between sites	Total Capacity	MSA Population
Boston	Massachusetts General Hospital	Tufts University Hospital	2 miles	6 Treatment Rooms	4.6 Million People
Oklahoma City	University of Oklahoma	Integris Health/Procure	17 miles	6 Treatment Rooms	1.3 Million People
Chicago	Central DuPage Hospital/Procure	Northern Illinois Proton Treatment & Research Center	12 miles	8 Treatment Rooms	9.5 Million People
Seattle	Seattle Cancer Care Alliance/Procure	Swedish Cancer Institute	8 miles	5 Treatment Rooms	3.4 Million People
Washington D.C (Proposed)	Sibley Memorial Hospital	MedStar Georgetown University Hospital	3 miles	5 Treatment Rooms	5.6 Million People

The Applicant projects the following average annual tumor specific patient mix for the proton therapy center:

	Average Annual Proton Therapy Patients	Percent Total
Pediatric Solid Tumors	152	17%
Adult Tumors:		
Brain and Spine	301	33%
Lung	123	13%
Head and Neck	114	12%
Prostate	89	10%
Sarcoma	50	5%
Pancreas	48	5%
Liver	40	4%
Total Adult	765	83%
Total Adult and Pediatric	917	

The Applicant proposes to dedicate one gantry room for pediatric patients and proposes to serve 152 pediatric patients a year. Sibley came to this conclusion by applying NCI SEER incident rates to the RSA pediatric population and projects that 30% of these cancer patients will require radiation therapy. This projection is based on the conclusion that only pediatric solid tumor patients are eligible for radiation therapy. Sibley also calculated that of the projected 171 pediatric cancer cases for proton therapy in the RSA, approximately 60% (104 patients) would seek care at Sibley. The Applicant projects that it could treat up to 45 additional pediatric patients from the ODSA and ISA, for a total of approximately 150 patients. The Applicant states that Sibley and Johns Hopkins visited the MGH Burr Proton Center to better understand and benchmark Sibley's academic program. During the site visit, it was learned that on average 17% of Burr's proton therapy treatment volume is pediatric patients. The Applicant adds that

it is important to note that from 2007-2011, the average number of pediatric patients seen at Johns Hopkins Hospital who would be eligible for proton therapy based on tumor type was 51. These patients are within the RSA, and therefore represent nearly half of the patients in need of proton therapy that are projected to originate from the RSA. The Applicant anticipates that the remaining pediatric proton therapy patients would be referred from the Sibley Proton Project's partners.

In conclusion, the Applicant maintains that the Sibley Proton Therapy Center:

- Has the resources to build and develop a proton center that will excel in all three domains of the Johns Hopkins Tripartite Mission: clinical care, training, and research;
- Includes sufficient capacity to care for referred pediatric cases, specifically-indicated adult tumors (head, neck, spine, etc.), and patients in clinical trials, as well as to allow access to the equipment for training and research;
- Provide access to comprehensive, coordinated pediatric radiation oncology, including proton therapy;
- Formalize partnerships with Children's National Medical Center, and among other institutions, to reach children in need of proton therapy; and
- Solidify partnership with Howard University to facilitate patient referrals and will also enable clinicians and trainees to gain expertise on this new equipment and with this treatment modality.

SHPDA staff reviewed demographic information on cancer patients in the District and found that according to the American Cancer Society, 2,950 District residents were diagnosed with, and 1,010 died from, cancer in 2012. Despite progress, cancer persists as the leading cause of premature (before age 70) death in the District, and as the

second most common cause of death overall, regardless of gender or race. In the District, African Americans had either the highest incidence or highest mortality rate for each of the identified cancers. African Americans also were most affected by such issues as lack of access, diagnosis at later stage, inadequate palliative care, and low participation in clinical trials. According to a recent Rand report, black residents in the District were 90% more likely to die from cancer in 2008 than white District residents. Overall, the District of Columbia has one of the highest cancer mortality rates in the nation, ranking:

- Higher than anywhere in the United States for prostate cancer;
- Second highest in the nation for breast cancer;
- Third highest in the nation for cervical cancer; and
- Seventh highest in the nation for all cancers combined.

SHPDA staff also reviewed scientific literature provided by the Applicant, including a study by ASTRO, whose purpose was to evaluate the state of science of proton beam therapy and arrive at a recommendation for the utilization of the technology. ASTRO routinely evaluates new modalities in radiotherapy and assesses the published evidence to determine recommendations for the society as a whole. ASTRO established a Proton Task Force to develop a report for the evidence based review of proton beam therapy. Data was reviewed for proton therapy in central nervous system tumors, gastrointestinal malignancies, as well as, lung, head, neck, prostate, and pediatric tumors. The following conclusions were made by the Report:

Central Nervous System Tumors

“Proton Beam Therapy has multiple theoretical advantages over photon radiotherapy for Central Nervous System tumors due to the ability of Proton Beam Therapy to deliver high dose radiotherapy with steeper dose gradients to proximal critical structures than can be achieved with photon radiotherapy. Clinical data from Proton Beam Therapy or mixed photon/Proton Beam Therapy for base of skull tumors appear superior to previously published series of conformal photon radiotherapy; however, stereotactic

photon radiosurgery may provide a significant dosimetric and clinical advantage to standard conformal radiotherapy techniques. Overall, more clinical data (published clinical trials) are needed to fully establish the role of Proton Beam Therapy in Central Nervous System tumors.”

Lung

“Proton Beam Therapy has been used in the treatment of stage 1 non-small cell lung cancer although no clear clinical benefit over photon therapy has currently been shown. Data regarding the use of Proton Beam Therapy in other clinical scenarios remain limited and do not provide sufficient evidence to recommend Proton Beam Therapy for lung cancer outside of clinical trials. In addition, unlike in some other disease sites, the issue of organ motion in lung cancer is critical and adds an additional challenge to the use of Proton Beam Therapy.”

Gastrointestinal

“Proton Beam Therapy is mostly untested in GI malignancies, and the number of patients with GI malignancies who are eligible for Proton Beam Therapy will be very small until indications for its use become clearer. In rectal and gastric cancers there appears to be little role for Proton Beam Therapy. In esophageal and pancreatic cancers there may be a rationale for Proton Beam Therapy, as these are two sites often with localized unresectable disease near critical organs at risk, but almost no clinical data exist. In hepatocellular cancer there appears to be the most data and perhaps promise for Proton Beam Therapy as an alternative to photon based approaches, but more rigorous study and prospective clinical trials are necessary to define the differences in toxicity and efficacy between protons and photons.”

Ocular Melanoma

“Proton Beam Therapy has been shown to be effective in the treatment of large ocular melanomas not approachable via brachytherapy. In the group of intermediate tumors that has been well studied by the Collaborative Ocular Melanoma Study group, there is

evidence for efficacy of both Proton Beam Therapy and brachytherapy. Further comparative studies will help select patients for the appropriate therapy.”

Prostate Cancer

“Prostate cancer has the most patients treated with Proton Beam Therapy of any other disease site. The outcome is similar to Intensity-modulated radiation therapy however, with no clear advantage from clinical data for either technique in disease control or prevention of late toxicity. This is a site where further head to head clinical trials may be needed to determine the role of Proton Beam Therapy. In addition, careful attention must be paid to the role of dosimetric issues including correction for organ motion in this disease. Based on current data, Proton Beam Therapy is an option for prostate cancer, but no clear benefit over the existing therapy of Intensity-modulated radiation therapy photons has been demonstrated.”

Head and Neck

“Proton Beam Therapy has been shown to be well suited to treat targets near critical structures, especially at the base of the skull. Data for sinonasal tumors specifically are encouraging, but further data are needed. However, until Intensity-modulated Proton Beam Therapy is more fully developed and tested, it will be difficult to establish whether Proton Beam Therapy may be equivalent to photon Intensity-modulated radiation therapy in treating full head and neck plans. At this time, further clinical data through prospective clinical trials are needed regarding cases in which the target is the primary volume located near critical structures. Currently, there are insufficient data to recommend Proton Beam Therapy for routine head and neck radiation therapy outside of clinical trials.”

Pediatrics

“Proton Beam Therapy has perhaps its most developed place in pediatric brain tumors. Although the clinical evidence is lacking, the rationale for using Proton Beam Therapy in posterior fossa tumors, optic pathway tumors, and brainstem lesions is compelling. Future clinical studies reporting on the outcome of patients treated with protons will

decide how widespread protons become for pediatric central nervous system tumors. There does not appear to be sufficient evidence at this time to recommend treatment with protons for non- central nervous system pediatric malignancies.”

ASTRO's Conclusion

ASTRO concludes that “(c)urrent data do not provide sufficient evidence to recommend Proton Beam Therapy outside of clinical trials in lung cancer, head and neck cancer, GI malignancies (with the exception of HCC) and pediatric non-CNS malignancies. In hepatocellular carcinoma and prostate cancer and [sic] there is evidence for the efficacy of Proton Beam Therapy but no suggestion that it is superior to photon based approaches. In pediatric CNS malignancies there is a suggestion from the literature that Proton Beam Therapy is superior to photon approaches but there is currently insufficient data to support a firm recommendation for Proton Beam Therapy. In the setting of craniospinal irradiation for pediatric patients protons appear to offer a dosimetric benefit over photons but more clinical data are needed. In large ocular melanomas and chordomas, ASTRO believes that there is evidence for a benefit of Proton Beam Therapy over photon approaches. In all fields, however, further clinical trials are needed and should be encouraged”.

It is clear that there is no consensus on the effectiveness of proton therapy. Some believe that the ability of proton therapy to minimize dose to critical structures makes it better than photon therapy for certain patients. Others maintain that it is simply another form of radiation therapy whose superiority to photon therapy is not established and is not worth the level of financial and other investments required. If there is any agreement, it seems to be that the technology is promising and that more rigorous studies and clinical trials are needed to clearly define the advantages and limitations of the procedure in disease control and prevention of toxicity.

Based on the scientific literature, there are indications that proton therapy may be the treatment of choice in some specific tumors. However, there is no concrete clinical evidence to show that proton therapy is overall clinically more effective than

conventional radiation. Most published data examining clinical use of proton therapy are single institution studies, and while these publications are of value, they are not randomized controlled trials which are the standard for evaluation and comparison of treatment techniques. The introduction of any new technology requires scientific investigation of risks and benefits associated with its use. To most radiation oncologists and physicists, the benefit of proton therapy in terms of science is without question; protons deliver more precise doses of radiation and allow sparing of normal tissue, which is unarguably beneficial to patients. Protons deliver the majority of their energy at a very narrow area within the body. The technology can help deliver the desired radiation dose to the tumor itself without much entry or exit dose beyond the tumor. It tends to spare the normal, healthy tissues while delivering a more curative dosage. The literature suggests that the modality has the potential to more effectively treat tumors that are close to critical organs and to lead to improved outcomes for specific patients.

Although more than 50,000 patients reportedly have been treated worldwide over the last 40 years, the clinical evidence is still evolving. Indications are that the potential of proton therapy has not been fully realized and that it may be the next standard in cancer treatment. Randomized controlled trials are, therefore, needed to answer the questions doctors, researchers, policy makers, insurers, and ultimately patients are asking concerning the quality and efficacy of proton therapy. Clinical trials are critical to the ultimate success of moving the technology forward.

During the review process MedStar Georgetown University Hospital (MGUH) provided comments on Sibley's proposed proton therapy project. MGUH stated that:

1. The Advisory Board need methodology overstates actual Proton Therapy demand. The methodology assumes that the need for Proton Therapy services should be based on the assumption that 7.5% of cancer patients require and will seek Proton Therapy services.

2. Sibley's proposed need for sixteen vaults in its designated regional service area will be completely served by existing and proposed vaults. The University of Pennsylvania in Philadelphia, the University of Maryland in Baltimore and Hampton University in Hampton, Virginia, which together have a total of 15 vaults will help meet the demand.
3. Sibley's primary service area need estimates do not support the need for a four vault facility. Sibley did not account for the University of Maryland project in Baltimore that also serves patients in the surrounding suburbs of Maryland.
4. There is no need for a dedicated pediatric proton therapy vault at Sibley due to the fact that Sibley does not have a pediatric oncology program. Additionally, Sibley's claims of serving approximately 150 patients a year is not supported by historical utilization of existing providers.
5. No need has been proven for the research vault. Dedicating a single vault only to research activities is an unnecessary, costly, even frivolous undertaking.
6. Sibley's reliance on Massachusetts General Hospital as its planning model in fact demonstrates that its four vault proposal is not needed. Sibley's comparison with Massachusetts General does not take into account another proton therapy provider in the primary service area, the University of Maryland facility in Baltimore.
7. Sibley's data on new center utilization and its theory of reliance on Hopkins referrals demonstrate its utilization estimates are unrealistic and unsupported. No current proton therapy facility has achieved serving 800 patients in a three year window.

SHPDA staff reviewed the information from MGUH and made the following observations:

1. SHPDA staff believes that the Advisory Board projection is simply an estimate to show the relative need of proton therapy services. SHDA staff understands that not all patients who might be amenable to Proton Therapy will actually be directed to this modality by their physicians.
2. SHPDA staff recognizes that other proton therapy facilities are or will be located in the Mid-Atlantic region and that the service areas overlap.
3. SHPDA staff understands that the University of Maryland is in the process of constructing a proton therapy center that plans to be serving patients in 2015. SHPDA staff recognizes that the primary service areas of the Maryland and Sibley facilities could partially overlap.
4. Sibley does not have a Certificate of Need or a license to serve pediatric patients and, as MGUH has stated, it is unclear as to how Sibley proposes to serve approximately 150 pediatric patients.
5. SHPDA staff strongly disagrees with MGUH that a research vault will not be needed. SHPDA staff believes that in order to advance the understanding of the usefulness of the technology research is essential to demonstrate the benefits and weaknesses of the technology. The scientific literature suggests that advanced clinical trials and further research are needed to determine the efficacy of the modality.

Given the incidence and prevalence of cancer in the District, I believe that there is a need to give patients the ability to access the most sophisticated and cutting-edge technology. There are a number of patients with tumors that are located in sensitive areas of the body, such as the brain and the spine, where radiation needs to be very focused, that can benefit from the procedure. Proton therapy can also help to improve overall treatment of patients with some tumors that do not respond very well to other treatment modalities. While currently proton therapy does many things that are similar

to what conventional therapies can do, because of its inherent physical advantage it is important to explore ways to develop innovative treatments and protocols. In short, it is important that academic centers and research facilities be given the opportunity to find ways to more effectively spare healthy tissues. Medicine can advance only when clinicians and hospitals undertake research and clinical trials.

**Age-Adjusted Incidence Rates by Sex and Race for Cancers Diagnosed in 2009, D.C. Residents
All Sites**

Race	<u>Male and Female</u>		<u>Male</u>		<u>Female</u>		
	Rate*	Count	Rate	Count	Rate	Count	
All Races	492.7	2,772	575.9	1354	442.2	1,417	2,772
White	423.0	709	425.5	325	440.1	383	
Black	507.5	1,830	627.5	913	432.9	917	

**Age-Adjusted Mortality Rates by Sex and Race for Cancer Deaths Occurred 2009, D.C. Residents
All Sites**

Race	<u>Male and Female</u>		<u>Male</u>		<u>Female</u>		
	Rate*	Count	Rate	Count	Rate	Count	
All Races	199.6	1,122	258.6	558	164.4	564	1,122
White	151.1	253	187.9	128	129.3	125	
Black	232.2	846	310.8	422	186.6	424	

* Rates are per 100,000 persons and are age-adjusted to the 2000 U.S. standard
All races includes White, Black and other races

Based on the information in the record, staff has determined, and I agree, that the Applicant has demonstrated the need for proton therapy services to serve adult patients. Given the incidence and prevalence of cancer in the District, it is important to have options of treatment modalities. The SHPDA is particularly encouraged by the commitment of the JHHS to strengthen cancer services in the District. The Applicant states that the integration of Sibley and Johns Hopkins brings the Sidney Kimmel Comprehensive Cancer Center to Washington, D.C. and the proton center will be part and parcel of the Kimmel Center. The program will be fully integrated with the clinical care infrastructure, quality protocols and clinical trials at the Kimmel Center.

The Applicant further states that the Sibley proton therapy center is going to be the only proton therapy center for Johns Hopkins and all its affiliates. It also maintains that Johns Hopkins is planning on building a significant cancer research, training, and care facility at Sibley. While it can be argued that as a free standing community Hospital, Sibley would not have had the infrastructure to establish proton therapy, with the involvement and commitment of Johns Hopkins the proposed project is a viable program. The arrangement will allow the transfer of clinical and research advances at Hopkins into clinical practice at Sibley.

However, the Applicant's proposal includes services to pediatric patients for which it does not have authority. The Applicant has emphasized the importance of proton therapy for pediatric patients and the benefits for children when compared with conventional radiation therapy. The Applicant proposes to serve approximately 150 pediatric patients, dedicate 1 of 4 treatment gantries for pediatric patients, and develop a comprehensive pediatric radiation oncology program at Sibley for pediatric patients. Nevertheless, the Applicant does not have a Certificate of Need or a license to serve pediatric patients. While the Applicant states that it will establish a partnership with Children's National Medical Center it is not clear what the terms and conditions of such an arrangement will be. The Applicant has filed a letter of intent with SHPDA for the establishment of pediatric oncology services. However, an application has not, as yet, been submitted and a decision has not been made. I have, therefore, concluded that the Applicant has not justified the need for pediatric services.

It must also be noted that the Applicant has stated that the services will be financially viable without the proposed pediatric component.

The SHPDA supports the Applicant's proposal to develop working relationships with Howard University Hospital and United Medical Center. If the commitment is there, the collaboration can help reduce health disparities and enhance access to treatment and to clinical trials by patients from underserved areas of the District. The collaboration may particularly help enhance Howard University's research capabilities and may increase

the involvement of minority patients in clinical trials. The medical staff of Howard University and United Medical Center may also be given opportunities for training.

2. Accessibility:

The Applicant states that the high cost of establishing a proton therapy is one of the reasons that there are currently only ten centers in operation in the United States. Sibley and JHM consider proton therapy to be a mission-centric imperative for the care of the cancer population in Washington, D.C. and across the region. Sibley and JHM plan to provide a safer clinical alternative to oncology populations by bringing all of JHHS's academic tradition, resources, and reputation to bear to help advance the development and evaluation of this technology. The Applicant maintains that the proton therapy center at Sibley will be the singular proton therapy service that will support the patient population of the entire JHHS community. The proton therapy radiation oncologist will work with multi-disciplinary oncology teams across JHHS to ensure that proton therapy is an integral treatment modality for all cancer patients. With the integration of a singular electronic medical record, patient referrals to the proton therapy center will be streamlined and the communication of clinical information will be directly accessible in real time to all Johns Hopkins providers.

According to the Applicant, the proton therapy center staff and physicians will be accessed via:

- Physicians within the Johns Hopkins family familiar with the uses of proton therapy;
- Physicians who are familiar with proton, but may not be affiliated or aligned with the Johns Hopkins facilities, such as Children's National Medical Center, Anne Arundel Medical Center, Howard University Hospital, etc.;

- Community physicians outside of the Sibley/Johns Hopkins medical staff who are familiar with the procedure and want proton treatment for their patients;
- Upon the request of another physician involved in the patients care; and
- Word of mouth from existing patients.

The Applicant maintains that physicians who are employed by Sibley, JHM, or Johns Hopkins Community Physicians do not discriminate against any individual on the basis of race, religion, sex, sexual preference, or handicap. All services are available regardless of a patient's ability to pay, source of payment, or the institutional affiliation of the patient's physician. According to the Applicant, through a proposed partnership with CNMC, Sibley and JHM are making a commitment for the accessibility of the services by children in the District and the larger catchment area typically served by CNMC. The payer mix typically seen at Sibley has a relatively low percentage of Medicaid patients, and also a low percentage of self-pay/charity care designations. The Applicant states that Sibley has taken into account serving a larger number of CNMC and Howard University Hospital referrals in the financial projections for this project. The proportion of patients with Medicaid coverage is over 50 percent at both of these partner hospitals.

The Applicant states that the proton therapy center will be fully ADA compliant and accessible by car. In addition, it is served by numerous bus lines and a shuttle bus service is available to patients and staff to and from the Friendship Heights Metro Station, running 6:00 a.m. - 6:00 p.m., Monday through Friday. The radiation center hours of service will be 7:00 a.m. to 5:00 p.m., with flexibility to extend to 7:00 p.m. In addition, should a patient need additional care, diagnostic imaging, laboratory tests, and other hospital related services are available on site.

While staff believes that the Applicant generally meets the criteria and standards of accessibility, staff recommends that the Applicant should and can do more to provide cancer care services in underserved areas of the city. The Applicant can help reduce

the rates of cancer in the District by providing educational, screening, and treatment services. Staff, therefore, recommends, and I agree, that as a condition of approval for a certificate of need, the Applicant shall be required to establish, operate, and maintain a cancer screening and treatment clinic in an underserved area of the District and provide a clear plan of implementation with its second quarterly progress report. In addition, in order to ensure that underserved, uninsured, under insured and minority patients will have access to proton therapy, the Applicant should be required to make arrangements with the D.C Primary Care Association, clinics, and hospitals that serve low-income, uninsured, and minority patients in order to ensure that the patients will have access to proton therapy services when they need the treatment.

3. Quality:

The Applicant states that Sibley is duly licensed by the government of the District of Columbia as an acute care hospital. The Hospital is also accredited by the Joint Commission. The Applicant maintains that Sibley complies with all licensing and regulations that govern the management of live radiation sources and radiation therapy technology in the District of Columbia. Sibley further states that it will be collaborating with Johns Hopkins to obtain accreditation of the radiation oncology program through the American College of Radiology.

According to the Applicant, Sibley, Johns Hopkins University, and JHHS have been actively collaborating to integrate their radiation oncology programs and enhancing the quality of the Sibley radiation oncology program by standardizing the radiation equipment and information systems at Sibley and John Hopkins. Additionally, the parties will standardize the patient information management systems for communication and collaboration on multidisciplinary patient care. They will also enhance access to new and innovative clinical trials, including advanced non-radiation emitting image guidance and motion management. The Applicant also states that Sibley is standardizing radiation oncology specific quality and safety programs with Johns

Hopkins. The collaborations that have already been completed and are in process to accomplish this integration include:

- Sibley department leadership is integrated under Dr. Theodore DeWeese, Chairman and Professor, Department of Radiation Oncology and Molecular Radiation Sciences for Johns Hopkins Medicine;
 - Sibley medical physics leadership is integrated under Dr. John Wong, Chief of Medical Physics and Professor, Department of Radiation Oncology and Molecular Radiation Sciences for Johns Hopkins Medicine;
 - Sibley oncology leadership is integrated under Dr. Irene Gage, Medical Director and Associate Professor for Oncology Services in the Johns Hopkins National Capital Region;
 - Sibley radiation oncology equipment and information systems at Sibley are integrated with Johns Hopkins;
 - Sibley's clinical trial research infrastructure and Internal Review Board is integrated with Johns Hopkins University; and
 - Safety, quality programming, and research are integrated with Johns Hopkins.
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- ✓ The first quality and safety research project collaboration between Sibley and Johns Hopkins which applied a Failure Mode and Effective Analysis study to the complex operational workflow of Sibley radiation oncology is completed; and
 - ✓ Sibley has integrated with the propriety Johns Hopkins University radiation oncology safety and quality reporting system.

The Applicant further states that it will:

- Integrate the Sibley radiation oncology quality management with the Johns Hopkins University Quality Management Program for Radiation Oncology;
- Integrate the Sibley Electronic Medical Record (EMR) with Johns Hopkins Health System investment in the EPIC EMR; and
- Complete a collaborative radiation oncology certification through the American College of Radiology. The certification will include Johns Hopkins Hospital, Sibley radiation oncology, and Johns Hopkins University radiation oncology at Suburban.

The Applicant states that the medical staff of Sibley is organized into clinical departments, each of which is led by a Chairman who is a member of the Executive Committee of the Medical Staff. Monthly meetings are conducted by the Chairman to review utilization and medical audits, statistics, and unusual cases along with re-admissions and length of stay concerns. The Applicant maintains that several peer review programs will be implemented to ensure the highest quality of care for patients including:

- Tumor Boards - In a multidisciplinary setting, radiation oncologists, medical oncologists, and surgical oncologists will review cancer cases and develop the best cancer care plan for the patient and will evaluate the patient for clinical trial eligibility;
- Multidisciplinary Clinic - As established at Johns Hopkins, the subspecialty clinic will provide a patient with a comprehensive review of their disease by a subspecialty trained radiation oncologist, medical oncologist, surgical oncologist, pathologist, and radiologist. During one day visit, the patient will be provided a fully comprehensive care plan that is customized for his/her disease;

- Proton Peer Review - The proton therapy faculty will meet weekly to discuss the potential proton therapy cases and will determine the best comprehensive radiation care plan specific for each patient. During this peer review, clinical trial eligibility will be evaluated for each patient;
- New Patient Peer Review - The proton therapy faculty will meet weekly to review the treatment plan for each new patient. This peer review process will ensure that the patient will be receiving the safest and highest quality proton therapy treatment; and
- On Treatment Review - On a weekly basis each patient will have their course of treatment and their medical condition reviewed and evaluated by the radiation oncology and medical physics. This ensures that the highest quality of care is delivered throughout the course of treatment, and that the patient's evolving response to treatment is continually evaluated and managed.

The Applicant maintains that the following staff will be utilized to ensure the highest level of safety and quality at the proton therapy center:

- Leadership - The clinical program will be led by Sibley proton therapy center medical director. Medical physics and medical dosimetry will be led by the Johns Hopkins Medicine Chief of Medical Physics. The proton center will also have a dedicated chief radiation therapist and a dedicated nurse manager;
- Radiation Oncologists - The Sibley proton therapy center will be staffed by five radiation oncologists, each of which will have a sub-specialty cancer focus, such as pediatrics, central nervous system, head and neck, and gastrointestinal;
- Radiation Therapists - The staffing for radiation therapist will ensure that three radiation therapists will be managing patient care and administering the proton therapy for each treatment room and the simulations;

- Nursing - Nursing support will be provided both in the clinical consultation setting and in the treatment setting. There will be sub-specialty trained advanced practice professionals and nurses to support the care of the adult and pediatric patients.

- Pediatrics - There will be a sub-specialized team of clinicians to ensure the highest levels of safety and quality for pediatric patients. The therapy center will have a dedicated team including a pediatric anesthesiologist, anesthesia prep and recovery nurses, and anesthesia technicians to ensure the safest care for a pediatric patient who requires anesthesia during treatment. The pediatric program will be led by a subspecialty trained pediatric radiation oncologist, who will be supported by a sub-specialty trained nurse and advance practice professional; and

- Staffing levels for medical physics and dosimetry will be determined by the Chief of Medical Physics and will comply with industry standards, such as the ASTRO Blue Book. The staffing plan includes a lead clinical physicist, a lead accelerator physicist, and 5 medical physicists to support the clinical practice. The plan also includes 5 medical dosimetrists.

According to the Applicant, professional staff are required to participate in continuing education in order to meet and exceed the highest standards of quality care. Continuing education activities often include seminars and other specialized training. Training for the nursing and technical staff is coordinated by a Clinical Nurse Specialist. Nursing staff of the department participate in education programs as well as any necessary equipment specific monitoring competency training. Staff is also trained in basic life safety, infant and adult CPR which is included in the Hospital wide training program.

The Applicant states that the Sumitomo Proton Therapy system is currently in the US Food and Drug Administration (FDA) 510(K) pre-market clearance review process. In 2010, Sumitomo began submitting information to the FDA in modules because it would

be difficult for FDA to review all of the information in a single 510(K) within the required 90 day review period. A modular 510(K) process is applicable to proton therapy systems, because these systems are quite complex, in terms of the documentation and validation requirements. The Applicant maintains that Sumitomo has submitted all six of the planned modules, including: detailed system descriptions, plans, and results for the system safety testing, hardware and software information, and the test plans for the final installation commissioning at the hospital site. The Applicant projects that the Sumitomo proton therapy system will be approved in the second quarter of 2013.

According to the Applicant, it is important to note that as a Class 2 product, the proton therapy system is viewed by FDA as an established technology, and generally prospective clinical trials are not required to support the 510(K) clearance. The FDA process basically requires Sumitomo to compare its device to one or more legally marketed devices, i.e. other proton therapy systems that have already achieved clearance, to demonstrate substantial equivalence, based on their safety and performance testing. The Applicant adds that the Sumitomo proton therapy system has been in operation in Japan since 2001 at the National Cancer Center Hospital and completed a process similar to the 510(K) conducted by the Japanese Ministry of Health.

Based on the above information, staff has determined, and I agree, that Sibley has met the criteria and standards for quality of care.

4. Continuity:

According to the Applicant, proton therapy is usually additive therapy to standard radiation oncology treatments and when available, these modalities work in conjunction with one another to treat the patient with increased success. The Applicant states that clinical trial research services will be integral to the Sibley proton therapy center with goals to develop a robust inventory of clinical trials that are specific to each cancer site and to evaluate each patient for clinical trial eligibility. Sibley and Johns Hopkins have

adopted the JHU Internal Review Board and completed the integration of radiation oncology information systems.

The Applicant maintains that Sibley has established transfer agreements with most of the hospitals in the area for regular patient transfers. Appropriate transportation arrangements are made in accordance with the patient's physical and mental condition, and may be provided by the metropolitan Police Department, the District of Columbia Fire Department, rescue squads, private ambulance companies, or by other means. A standardized transfer form, utilized by all metropolitan area hospitals, is completed by the appropriate personnel prior to the patient's discharge or transfer to another facility. Other Sibley support services including, but not limited to, housekeeping, laundry, medical supply, laboratory, pharmacy, diagnostic imaging, dietary, medical records, and infection control will continue to be provided as they are currently at Sibley.

The Applicant states that Sibley and JHU are partnering with CNMC to improve the comprehensive oncology care that will be provided to the pediatric patients. According to the Applicant, the following describes the collaborative programs that will be included in the partnership:

- JHU and CNMC will jointly recruit a sub-specialty trained pediatric radiation oncologist who will provide clinical services at Sibley and CNMC;
- Sibley, JHU, and CNMC will collaborate in the development of a pediatric radiation therapy program which includes dedicated patient navigation, a pediatric anesthesia program and infrastructure, and a pediatric trained nursing team. Pediatric anesthesia is a critical component of the program because 30-40% of pediatric patients will require anesthesia during treatment;
- Sibley, JHU, and CNMC will collaborate in the development of the pediatric proton therapy service at Sibley; and

- JHU and CNMC will collaborate in pediatric oncology research, for which the faculties of both institutions are leaders in the international research community, and in the training of pediatric oncologists.

Additionally, the Applicant has provided memorandums of understanding for the provision of proton therapy services with York Hospital and Howard University Hospital.

After a review of the information, I have determined that Sibley is consistent with the criteria and standards of continuity of care.

5. Acceptability:

The Applicant maintains that Sibley is committed to providing quality healthcare, which is fully satisfactory to patients, their families and physicians. Sibley recognizes and supports the Patient's Bill of Rights, as established by the American Hospital Association. Hospital officials are personally available to respond to customer grievances whenever possible. When a customer complaint is received, it is investigated immediately. Remedial action is taken as appropriate and the affected parties are informed of the resolution.

The Applicant states that Sibley and Johns Hopkins are experienced healthcare providers and are committed to providing healthcare to achieve the highest value and best experience for patients. Additionally, they believe that it is important to acquire and adopt the latest innovations and discoveries for the benefit of the patients. According to the Applicant, each expansion and new program is motivated by the goal to provide exceptional care to the people and communities that Sibley serves.

Sibley maintains that it has presented information to the Advisory Neighborhood Commission (ANC) at one of their regularly scheduled meetings concerning the proposed project. The SHPDA has received letters of support from Walter Reed,

CNMC, York Cancer Center, DC Councilmembers, and the Federal City Council recommending approval of the proposed project.

At the public hearing that was held on January 8, 2013, many interested/affected parties provided testimony. Dr. Dunmore-Griffith, Interim Chairman of the Department of Radiation Oncology at Howard University Hospital said that the Proton Therapy builds on a long-standing collaboration between Howard and Hopkins. The partnership, she said, is dedicated to building cancer research capabilities at Howard University Hospital and enhance minority recruitment to cancer research programs at Johns Hopkins. Additionally, she noted that medical oncology fellows from Howard go to Hopkins to receive training. She further stated that Howard and Sibley have agreed to work together to develop training programs to ensure that practicing and future physicians with Howard University can include proton therapy in their treatment options for patients. Since Howard University treats a substantial number of African-Americans, she said that Howard's participation in the proposed program will ensure that research programs will include patients from all demographics. This is particularly important in view of the fact that cancer is a leading cause of premature death in Washington, D.C. Dr. Dunmore-Griffith also stated that many people would benefit from proton therapy and it will provide access to services for her patients.

Dr. Jay Loeffler, Chair of the Department of Radiation Oncology at Massachusetts General Hospital, where they operate a proton therapy center, said that the first patients were treated in the 1960s at Harvard and that Mass General established its facility in 2001. He also noted that the Hospital has received approval to acquire a second unit. He further stated that a large percentage of their patients are on clinical research trials and noted the need to study the effectiveness of the technology. He also stated that they are looking for other academic partners to perform clinical research. He concluded by saying that it is important that an elite group of institutions are involved in proton research.

Dr. Cyril Allen, the Chief Medical Officer at United Medical Center (UMC), stated that he supports the establishment of proton therapy at Sibley. He said that the potential benefits of establishing proton therapy at Sibley are very significant for UMC. He said that the program will foster collaboration with Sibley, Howard, and UMC that will benefit the residents of D.C. and, specifically, of Wards 7 and 8. He said that the collaboration will include an outpatient cancer clinic. As part of the effort, Howard will provide physicians and physician fellows who will see cancer patients at UMC, and the program will minimize the time between cancer being detected and the disease being treated. Dr. Allen noted that across the country overall cancer mortality is 21% higher among blacks than among whites. He further stated that the disparity is much greater in the District where overall cancer mortality among African-American residents is 80 - 90% higher than mortality among white residents. He also reported that cancer mortality is highest in Wards 5, 7, and 8, neighborhoods with the highest concentration of African-Americans and low income citizens. Dr. Allen also said that another significant component of the collaboration is that Sibley, Howard, and UMC will work to provide prevention and detection screening at UMC and to develop educational materials.

Dr. Sarah Horton, a Medical Oncologist and Director of Clinical Trials at Howard, said that she supports Sibley's proton therapy project. She said that they are currently working with Hopkins and said that the potential for more clinical trials at Sibley is of interest to them. She said that the Sibley proton therapy program will be an outstanding advantage to the Howard community.

Similarly, Dr. Carla Williams, a clinical psychologist and Associate Professor in the Department of Medicine at Howard University, said that the Howard-Hopkins partnership has strengthened cancer research capabilities at both Howard and Hopkins. She said that the Sibley proton therapy center presents another opportunity for partnership and collaboration. She said that disparities in incidence and mortality suggest that research needs to focus on a variety of explanatory factors, including how differences in access to and utilization of health care impacts cancer outcomes. She noted that the proton therapy center is research-focused and said that enhancing the

diversity of research for minority and under-served populations is important. She said that establishing the Sibley proton therapy center will help reduce disparities and increase access to clinical trials and treatment for patients in the region.

Based on the above, I have determined that Sibley is consistent with the criteria and standards for the acceptability of care.

6. Financial Feasibility:

The Applicant states that the proposed capital expenditure for this project is \$129,900,000. The Applicant initially maintained that the following sources of funds would be used to finance the project:

\$40 million of short-term debt:

The Johns Hopkins Health System currently maintains a Moody's credit rating of Aa3. The Health System also maintains a balance sheet that has the ability to absorb the additional debt. The short term debt will be issued by the Johns Hopkins Health System, guaranteed by Sibley Memorial Hospital, and is assumed to have a five year term.

\$20.3 million of philanthropic support:

The Sibley Memorial Hospital Foundation will work closely with the Johns Hopkins Health System to raise the necessary amount of philanthropic support.

\$15 million Sibley cash contribution:

Sibley Memorial Hospital and its controlled affiliates had approximately \$165 million of unrestricted cash and investments as of October 31, 2012, excluding over \$435 million that has been internally restricted by the Board of Trustees.

\$2 Million Sibley provision of land:

Sibley will provide the land on the Sibley Memorial Campus where the proton therapy center will be built.

\$25 million JHHS cash contribution:

The consolidated Johns Hopkins Health System had approximately \$1.5 billion of unrestricted cash and investments as of October 31, 2012.

\$25 million external investors:

Discussions with several potential external investors are underway.

The Applicant provided credit ratings from Standard and Poors, Fitch, and Moody's for JHHS to demonstrate that JHHS has the ability to borrow \$40 million. Additionally, the Applicant has supplied Sibley's credit rating from Moody's that was rated as A2.

According to the Applicant, the project is financially viable in the long run for Sibley and JHHS. The Applicant states that the charge per treatment is about \$1,500, and that the total cost per patient treatment could be approximately \$60,000. The Applicant states that it conducted a sensitivity analysis that demonstrates that either patient volumes or reimbursement rates have to decrease by more than 50% before the proton therapy center will go below the break-even point.

The Applicant proposed that philanthropic funds and money from external investors will easily be secured once the CON has been approved. The Applicant stated that its Foundation Boards have begun planning internally for the fundraising required for this project. The Applicant anticipated that, given the lead time to build this project, and given the previous track record of Sibley and Johns Hopkins fundraising efforts, the proposed \$20.3 million should not be difficult to secure. The Applicant also maintained that the other \$25 million is planned to be secured from external non-profit healthcare entities. Sibley reported that it has approached and held discussions with several non-profit healthcare entities regarding an equity investment in the proton project. While indicating that it is for informational purposes, the Applicant also stated that the project will be owned by a limited liability company to be formed under the laws of the District of Columbia.

During the review period of the application, MGUH has repeatedly raised questions about who the applicant is for the Sibley Proton Therapy Center and how the project will be financed. MGUH maintains that given the way the funds for the project are going to be raised some other unknown entity should have been the Applicant. This is because, MGUH maintains, Sibley states that among the sources for the proposed \$129 million capital expenditure are a) unknown equity investors, b) unknown philanthropic donors, and c) an unknown lender. MGUH states that the true ownership structure of the proposed Sibley proton therapy center is not clear. MGUH further states that in addition to ownership uncertainties, there are funding uncertainties with the Sibley application. MGUH argues that no sure financing commitments have been put forward by Sibley since the lenders, investors and donors are not clearly identified. In short, MGUH maintains that it is not clear what entity will purchase, build, and own the proton therapy center's building and equipment. It goes on to say that the wrong Applicant has filed the Sibley application, and that some other unnamed LLC seeks to undertake CON reviewable events without so filing.

On its part, in response to questions raised by SHPDA staff and MGUH, Sibley states that while it has been considering investors and partners, it will be the only owner and operator of the proton therapy center. Sibley maintains that it is paying for the center with its own funds and a \$25 million grant from Johns Hopkins. Sibley further states that while philanthropic gifts may in part offset Sibley's cash contributions, Sibley is committed to fund the project without such gifts, and gifts will not change Sibley's ownership.

To this end, the Applicant has provided resolutions from the Johns Hopkins Hospital, JHM and JHHS Board of Trustees approving the finances of the proposed project. The Applicant has also provided a resolution from the Sibley Board of Trustees that approves "(a) the Project; and (b) proceeding with the Project regardless of whether any donations or equity contributions can be obtained, with the Lucy Webb Hayes National Training School for Deaconesses and Missionaries in such event to provide any and all additional funds needed for the Project in the absence of any such donations or equity

contributions, and (c) the taking by Management of any and all actions necessary to fund, finance or otherwise pay the costs associated with the project.” The Applicant states that Sibley Memorial Hospital will operate and manage the Sibley Proton Therapy Center and will bear all costs associated with the operations and management of the facility. The Applicant states that it is committed to funding the project regardless of whether certain equity and philanthropic funding sources are realized. It goes on to state:

“Sibley will be the only owner and operator of the Proton Therapy Center. Sibley is paying for the center with its own funds and a \$25 million grant from Hopkins. Philanthropic gifts may in part offset Sibley’s cash contribution, but Sibley is committed to fund the project without such gifts, and in any event, gifts will not change Sibley’s 100% ownership. In keeping with Sibley’s commitment to collaboration, Sibley’s partners – including Howard, United, and CNMC – may desire future investment opportunities, but Sibley guarantees full funding of the project. If at some time in the future there is a proposal to change the ownership structure to include one or more equity investors, we will consult SHPDA and follow appropriate procedures before there is any change in the ownership”.

Based on the above considerations, I am satisfied that Sibley has demonstrated that it is the sole Applicant and that its Board has authorized that the project be funded without reliance on external sources. The Applicant has also provided information to show that it has the resources to fund the project. While it is true that during the review period Sibley’s information on the funding sources was not clear, the Sibley Board has now made it certain that the funds should be allocated by the Hospital.

C. Compliance with Uncompensated Care Requirements:

The Applicant has reiterated its commitment to provide uncompensated care to needy patients. I am, therefore, satisfied that the Applicant is consistent with the requirements.

D. Conclusion:

After a careful review of the application, the staff report, the recommendations of the Project Review Committee, the Statewide Health Coordinating Council, and the full record, I have determined that Sibley Memorial Hospital has demonstrated the need for the establishment of proton therapy services for adult patients. Given the incidence and prevalence of cancer in the District of Columbia, there is a need to develop advanced oncology treatment technology. It is important to have different options of treatment modalities. The commitment of JHHS to strengthen cancer services in the District should also be encouraged. While there are no long-term studies that provide evidence of the superiority of proton therapy over photon therapy, the science of proton promises significant technical advances. This seems particularly true for tumors that are located near critical structures such as the brain, the spinal cord, and the eye. If a tumor is located near the spinal cord, for example, the choice is between treating the tumor and risking paralysis or not effectively treating the tumor. It is anticipated that with the advancement of proton therapy, physicians may be able to avoid such difficult dilemmas.

Although it can be argued that as a free standing community hospital, Sibley would not have had the infrastructure to establish proton therapy, with the involvement and commitment of Johns Hopkins, the proposed project is a viable program. According to the Applicant, the program will be fully integrated with the clinical care infrastructure, quality protocols, and clinical trials at the Kimmel Center. It is important to note that the Sibley proton therapy center is going to be the only proton facility for Johns Hopkins and all its affiliates.

One of the down sides of proton therapy is that it is very expensive to acquire and operate. The technology costs tens of millions of dollars, or 20 to 30 times more than existing technology. The operation of a proton facility also requires highly trained medical and technical staff. In addition to the clinical staff, the operation must have a team of physicists and engineers to maintain and operate the particle accelerator. The

space requirements are also enormous. Some argue that the opportunity cost of the resources required makes the establishment of a proton facility unsupportable. It is said that the millions of dollars that are needed to establish a facility that treats relatively few patients are not justified, and that it would be more prudent to spend the resources in early intervention efforts to prevent cancer. It is also pointed out that all the money is spent on a technology whose efficacy has not been clearly demonstrated.

What is clear, however, is that proton therapy is an evolving technology and that there is a need for continued research to refine and improve the usefulness and applicability of the procedure. It is, therefore, important to have the service established in institutions that have the clinical, research, and educational components and are in a position to move the technology forward through appropriate clinical trials and biologic and DNA research.

While it is true that the SHPDA must work to keep health care costs down, it must be balanced with efforts to ensure that medical innovation and access to cutting-edge treatment are not stifled. Medicine can advance only when clinicians, hospitals, and research institutions undertake rigorous clinical trials. I, therefore, believe that the establishment of the service will not only provide treatment to patients whose tumors are not amenable to conventional radiation, but will help advance research to control cancer, and to provide education, and training to health care professionals and medical students.

Based on the above considerations, I have reached the following conclusions:

1. The Applicant has emphasized the importance of proton therapy for pediatric patients and the benefits children would get from receiving proton therapy over conventional radiation therapy. The Applicant proposes to serve approximately 150 pediatric patients, dedicate 1 of 4 treatment gantries for pediatric patients and develop a comprehensive pediatric radiation oncology program at Sibley for pediatric patients. But the Applicant does not have a Certificate of Need or a

license to serve pediatric patients. While the Applicant states that it will establish a partnership with Children's National Medical Center, it is not clear what the terms and conditions of such an arrangement will be. The Applicant has filed a letter of intent with the SHPDA for the establishment of pediatric oncology services. However, an application has not as yet been submitted and a decision has not been made.

As a result, I have determined that the request to provide proton therapy to pediatric patients be denied, and consequently there is no need for one of the proposed treatment gantries.

2. The Applicant has demonstrated the need for the establishment of proton services for adult patients. The facility will not only provide treatment but will advance research and help in the education and training of health care professionals and medical students. Specifically, the services will help to improve treatment to patients with tumors that currently do not respond very well to other treatment modalities that are available. It is a way not only to help patients but also a mechanism to finding better treatment for cancer.

However, given the current stage of the technology and the likely demand for services, the Applicant has not demonstrated the need for the operation of four gantries. The Applicant has not demonstrated that there will be a high demand for the services in the first few years of operation. At this time proton therapy may be the treatment of choice for few specific tumors. But there is no sufficient evidence that it is superior to proton therapy in treating most malignancies or that the demand for services will be high. This means that all gantries are not likely to be fully utilized in the first few years of operation.

The Applicant states that newly established proton therapy centers often keep their volumes low for reasons such as learning the new equipment and software, and establishing safe, quality treatment protocols. "As a result", the Applicant

states, "most proton facilities deliberately limit the utilization of their systems for a year or more". The Applicant also states that "established therapy centers treat twice as many patients as newly established proton centers". This indicates that there is an extended ramp-up period for the services. I understand that it is not uncommon for facilities to initially operate one or two gantries and defer the installation of additional rooms. The Applicant also states that "utilization is dependent on the age of the proton center in the market". This further indicates that the demand for the services is not likely to be high for several years after the facility is established.

I have, therefore, determined that the Applicant build and operate two treatment rooms - one for patient care and the other one for research¹. The Applicant states that one of the treatment rooms will be specifically for research purposes and that 20 to 25 percent of the patients will participate in clinical trials. The research will help identify better ways to treat patients with cancer and to figure out when and how best to use the technology. The availability of the treatment services will ensure that residents will have access to needed services close to home. It is burdensome on patients and families to travel to other cities given the need for multiple treatments.

It must be noted that the Applicant states that Sumitomo produces custom proton therapy systems which can be combined and assembled in a variety of ways that meet the specific needs of the customer. This suggests that the facility can begin operations with the two gantries, and expand as the theoretical advantages of the modality are clearly established in practice and as the demand for service increases.

¹ This decision does not preclude the Applicant from applying for a certificate of need for more gantries if the need arises for additional capacity or to expand the scope of the services.

In summary, I have decided to approve the establishment of adult proton therapy services with two gantries, and to deny the provision of services to pediatric services at Sibley Memorial Hospital.

Cancer mortality is highest in areas of the District which have large concentrations of African-American, Hispanic, and low-income residents. The higher overall cancer incidence among black District residents is attributable to a higher incidence of colorectal, lung, and prostate cancers. The problem is compounded by the fact that many residents do not have the knowledge or financial means to seek and receive medical care before their cancers progress. It is reported that newly diagnosed cancer patients in the District are more than twice as likely to seek care with Stage IV cancers if they are uninsured or underinsured. This is partly attributable to the fact that patients in underserved areas do not have ease of access to adequate screening to prevent and detect cancer. The problem is compounded by the fact that screening results are frequently not acted upon in a timely manner due to lack of follow up.

As a result, while efforts to cure and control the disease are important, there is a need to redouble efforts in the area of prevention and early detection. Education programs have to be developed to change the culture and encourage residents to get checked, to seek help early and frequently, and to follow up when a problem is indicated. Screening tests are very important because they can help find cancer at an early stage, before symptoms appear, and when treatment is more effective and cure is possible. But since screening results may not lead to clear diagnosis by themselves, more tests are frequently required to determine the nature and scope of the problem. As a result, it is crucial that uninsured and underinsured patients are given access not only to screening but also to follow up diagnosis and treatment.

During the review period, the Applicant has indicated its commitment to establish a cancer screening and treatment clinic in an underserved area of the District in collaboration with Howard University Hospital and United Medical Center. However, while a cooperative approach is to be supported, it must be clear that the responsibility

of establishing and operating the clinic is that of Sibley Memorial Hospital and not that of its partners. With or without partners, Sibley is expected to be the sole responsible party to establish a clinic in an underserved area and to offer educational, screening, treatment and follow up of cancer services.

In addition to a physical clinic for screening, evaluating and treating cancers in an underserved area of the District, the Applicant should propose and deploy an educational program for the underserved population in which fear of cancer and distrust of the medical establishment is a known barrier to seeking care. Lack of understanding of the importance of early detection, and poor knowledge of modern cancer treatment continues to contribute to poor outcomes for District residents. The Applicant should design and deploy a cost-effective, community-based education program as well as providing an annual summary documenting its effectiveness in terms of citizen contact and, ideally, changes in behavior.

It must also not be forgotten that establishing a clinic in an underserved community will benefit the teaching programs of the Applicant. Exposure to an additional large population of patients, some with challenging medical and oncological conditions, will likely enhance post-graduate training of fellows and residents. Such a clinic will also benefit the District more broadly by helping to diminish the perception of a health care divide between the various wards of the city.

I have, therefore, determined that, as a condition of certificate of need approval, the Applicant shall be required to address some of the disparities in cancer education, screening, and treatment in the District, particularly access to services by underserved residents as follows:

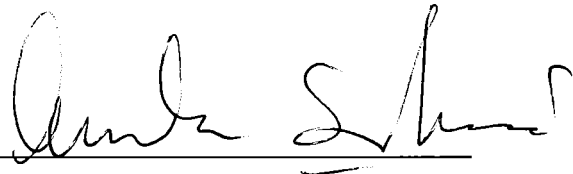
- Given the incidence and prevalence of cancer in the District of Columbia and given the health disparities in the city, the Applicant shall , in consultation with the Department of Health, establish, operate and maintain a full time cancer screening and treatment clinic in one of the underserved areas of the District in

Ward 5 or 8, particularly to prevent and treat the most common cancers – breast, lung, prostate and colorectal - and provide a clear plan of implementation with its second quarterly progress report;

- In order to ensure that underserved, uninsured, under insured, and minority patients have access to proton therapy treatment, the Applicant must enter into clear arrangements with the D.C. Primary Care Association, clinics, hospitals, and other entities that serve these patients and establish mechanisms to facilitate access to the proton therapy services and report to the SHPDA with its first year progress report; and
- Provide to SHPDA annually information on the proton therapy utilization and on the operations of the cancer screening and treatment clinic, including the number of patients served, the diagnosis, source of payment, source of referral, as well as the race, age, sex, ward, and zip code of the patients.

May 31, 2013

Date

A handwritten signature in black ink, appearing to read 'Amha W. Selassie', written over a horizontal line.

Amha W. Selassie
Director